Description

CARRIER MEDIUM FOR ANALYZING A SUBSTANCE

BACKGROUND OF THE INVENTION

The <u>present</u> invention relates <u>in general</u> to <u>the field of testing for various physical conditions</u>, and in <u>particular to</u> a carrier medium for analyzing an analyte. <u>In addition</u>, the method relates to a method for producing such carrier media, as well as a device and a method for reading such carrier media.

Carrier media are known which are used for the purpose of testing an analyte in regard to for a specific condition. To this end, a biological or chemical substance is applied to the carrier medium, the substance either reacting or not reacting upon contact with the <u>analyte</u> substance <u>being tested</u>, depending on the <u>presence or absence of a corresponding specific physical condition. As a rule</u>, Typically, the reaction is manifested by a color change in the carrier medium. Known carrier media include, for example, those which, when they come in contact with a liquid, change color in response to the pH of the liquid; or carrier media which, upon contact with urine, indicate whether <u>or not</u> a pregnancy is present. Carrier media coated with an antibody are able to verify through a color reaction whether or not the associated viruses are present in the blood of a patient.

AThe disadvantage of carrier media of this type is the fact that an analyte may be tested only for a single condition per carrier medium. If a number of analyses for different conditions are to be made on the analyte, a time-consuming and costly analysis at a physician's office is required involving multiple carrier media, and a large quantity of the analyte such as blood or urine-is required.

What is needed is The goal of the invention is therefore to provide a single carrier medium

which that is suitable for multiple analyses, thereby offering a method of analysis to the patient that is both convenient, and also saves time and expense, and requires

Implicit in a carrier medium of this type is the fact that smaller quantities of biological or chemical material substances and analytes are required to carry out the multiple analyses. It is thus the goal of the invention to provide a method for producing and reading these carrier media, which media are nevertheless commercially profitable for the producer of the biological and/or chemical substances. The goal of the invention is thus to provide a method for reading the carrier media which allows for a_cost-effective accounting of the reading. Another goal of the invention consists in providing a device for reading the carrier media according to the invention, which device is capable of reading the carrier media in terms of the method according to the invention.

The goal of the invention is achieved by a carrier medium for analyzing an analyte according to Claim 1, a method for producing carrier media according to Claim 12, a device for reading a carrier medium according to Claim 19, and a method for reading carrier media according to Claim 24.

SUMMARY OF THE INVENTION

In a carrier medium having at least two defined regions, biological and/or chemical substances are applied to the regions of the carrier medium according to the invention for analyzing an analyte, which The carrier medium is additionally also provided with a code that indicatesing which biological and/or chemical substance is located in which defined region. The application of multiple biological and/or chemical substances to one carrier medium enables multiple analyses to be performed simultaneously on the analyte. This approach reduces the required quantities of the biological and/or chemical substances needed to perform the desired analyses of the analyte. The

carrier medium itself does not reveal which biological and/or chemical substance is located in which region; this information <u>may is instead be</u> provided only by the code—which indicates which substance is located in which region.

Preferably, sSeveral hundred biological and/or chemical substances are may be applied in a corresponding number of defined regions on the medium. As a result, several hundred analyses may be performed simultaneously on an analyte such as blood or urine, using a single carrier medium, thereby saving considerable time and expense.

Preferably, tThe biological and/or chemical substances are may be arranged differently within the defined regions on two different carrier media. As a result, it is may not be possible to draw conclusions from the arrangement of the biological and/or chemical substances on one carrier medium about the corresponding arrangement of biological and/or chemical substances on a second carrier medium. It is only by reading the code on a particular the carrier medium that it may be possible to determine which biological and/or chemical substance is located in which region on that particular medium.

Preferably, t<u>T</u>he defined regions are <u>may be</u> arranged differently on two different carrier media. As a result, it <u>is may</u> not <u>be</u> possible to draw conclusions from the arrangement of the defined regions on one carrier medium about the arrangement of the defined regions on a second carrier medium. In particular, t<u>T</u>his design for the carrier medium provides an additional means of encoding.

Preferably, aA temperature sensor for detecting ambient temperature is may be provided on the carrier medium in order to record any improper storage of the carrier media at excessively high or low temperatures.

In an advantageous embodiment of the invention, tThe code is may be a barcode, a numerical code, or an alphanumeric code, or the code is may be provided by the arrangement of the defined

regions on the carrier medium. This last implementation variant for the code, in particular, is preferred may be useful when since no space is provided on the carrier medium for a barcode or other type of discrete code, so that instead the code is indicated by the arrangement of the defined regions.

Preferably, tThe code may provides information to a device reading the carrier medium as to how the device should read the defined which regions. For example, if certain biological and/or chemical substances respond in a completely different wavelength region than other biological and/or chemical substances, the code may contain this information and instruct the reading device to set specific detectors for the reading in accordance with the expected wavelengths to be detected.

Preferably, tThe code may contains information about the expiration date of the carrier medium. After specific storage periods, certain biological and/or chemical substances react to form different substances and, as a result, may no longer be used for the designated analyses. As such, Tthe code is able to may pass on the appropriate information to a device reading the carrier media such that a corresponding warning may be issued by the reading device in the event if a carrier medium is used after the expiration date.

In an advantageous embodiment of the invention, tThe code of the carrier medium may contains information about the storage of the carrier medium from the time of manufacture to the time the carrier medium was used. For example, Ccertain biological and/or chemical substances typically may must-not be stored above or below specific temperatures, as otherwise certain undesirable reactions occur. Thus, the carrier medium preferably may contains means for detecting the ambient temperature whereby ifin the event certain temperatures are exceeded, either on the high side or low side, these variations are stored in the code. If such a carrier medium is nonetheless used for an analysis, the reading device is able to detect based on the code that the carrier medium has not

been stored according to specification and issue a warning to this effect.

The carrier medium is advantageously may be composed of a film strip, glass carrier, or paper.

Preferably, tThe biological and/or chemical substances used are may be DNA, RNA, proteins, or antibodies. As a result, analyses may be performed focusing on bacteria or viruses.

The A method according to the invention for producing the carrier media comprises the following steps:

- a. producing a set of identical carrier media having a first arrangement of the defined regions and/or a first arrangement of the biological and/or chemical substances within the defined regions;
 - b. assigning a different code to each of these carrier media in the set;
- c. storing the arrangement of the defined regions and/or the arrangement of the biological and/or chemical substances within the defined regions of the carrier media along with the associated codes;
- d. selecting a second arrangement of the defined regions, and/or of the biological and/or chemical substances in the defined regions, that is different from the first arrangement;
 - e. implementing steps a through c for the second arrangement; and
- f. implementing steps a through c for subsequent arrangements different from the arrangements already-previously used.

This production method ensures that each individual carrier medium produced receives a different code, and that the code is stored along with the associated arrangement of defined regions and/or with the arrangement of biological and/or chemical substances in the defined regions. While a certain number of carrier media are thus produced which have an identical arrangement of defined regions, and/or of biological and/or chemical substances in the defined regions, nevertheless these

carrier media are differentiated by their corresponding codes, with the result that no two carrier media identical in every respect are produced, and when two carrier media are compared it is <u>likely not impossible</u> to detect which biological and/or chemical substance is located in which defined region.

Preferably, tThe code is may be provided by a simple numbering of the carriers. A code of this type is may be the simplest means of providing the different carrier media with different codes.

Preferably, tThe biological and/or chemical substances <u>may be are printed</u> on the defined regions of the carrier media with a print head analogous to that used in an inkjet printing process. As a result, the carrier media may be produced in a <u>particularly relatively</u> inexpensive manner, while the defined regions are able to be locally placed with high precision on the carrier media.

Preferably, oOne set <u>may comprise</u>consists of approximately 1,000 to 10,000 carrier media., and Several hundred <u>different</u> sets <u>may be are advantageously</u> produced. As a result, a large number of carrier media are produced whereby the carrier media are present in different forms.

One type of carrier medium each may be is advantageously selected from each of the various sets, and these selected carrier media are may be packaged together. As such, Oone pack thus contains only carrier media with different arrangements and, as a result, it may not be possible is impossible to draw conclusions from the arrangement on one carrier medium about the arrangement of a second carrier medium in the same pack. Since ideally the various packs are may be distributed throughout a given country, or are even distributed worldwide, the probability that a given user maywould receive carrier media having identical arrangements (although with different codes) is extremely low.

Alternatively, multiple sets of carrier media are may be mixed and randomly selected for inclusion in a common pack. As such, In this approach, the possibility cannot be excluded that two

carrier media with identical arrangements are may be included in one pack, although the probability of this occurring is relatively low given a sufficient number of different sets.

A_The-device according to the invention-for reading a carrier medium according to the invention has at least one optical detector per defined region, with tThe optical detectors detecting the reactions of the biological and/or chemical substances in the defined regions as soon as when the control device carrier medium has been brought into a read position relative to the device.

Preferably, tThe device may havehas means for acquiring and transmitting the code to an administrative center. The device itself is may not be able to determine the arrangement of the read carrier medium read from the code since if the arrangement of the defined regions, and/or the arrangement of biological and/or chemical substances within the defined regions, along with the associated codes, are not stored within the reading device. As such, Iit may is therefore be necessary to transmit the code to an administrative center in which the specific arrangement corresponding to the extracted code is determined. The device itself is may only be able to detect in which defined region a reaction of the biological and/or chemical substances has occurred in response to the analyte; it is may not, however, be able to indicate which biological and/or chemical substance has reacted.

The optical detectors of the device are preferably may be semiconductor chips.

Means for digitizing the detected signals and/or transmitting the detected signals to the administrative center are preferably may be provided in the device so that the detected signals are able to may undergo subsequent processing in an optimal manner.

The A method according to the invention for reading a carrier medium according to the invention in conjunction with the use of a device for reading the carrier medium according to the invention comprises the following steps:

- a. applying the analyte to the carrier medium;
- b. moving the carrier medium into the read position relative to the device for reading the carrier medium;
 - c. transmitting the code of the carrier medium to an administrative center; and
- d. within the administrative center, evaluating the code and determining the associated arrangement.

The An advantage of the method according to the invention for reading a carrier medium is lies in the fact that it provides the manufacturers of the carrier media or of the biological and/or chemical substances, and/or the medical insurance company, with a profitable accounting system. The application of several hundred different biological and/or chemical substances onto a carrier medium means that significantly smaller quantities of these substances are required. The quantities required here may be reduced by a factor of between 10⁶ and 10⁹. An new accounting system is may nevertheless be needed in order to ensure that the production of these biological and/or chemical substances remains profitable.

The fact that such carrier media are produced in relatively large quantities, since they provide a simple test for certain diseases, bacteria or viruses, and are thus used utilized frequently by people, does not compensate for the loss generated by the smaller required quantities. For this reason, the method according to the invention of reading the carrier media may leaves evaluation of the carrier media to a central administrative center. Although the inventive design of the carrier media and of the device for reading a carrier medium does—may—enable a person to detect reactions of the biological and/or chemical substances to the analyte, the person himself is may not be able to correlate the detected signals reactions with specific biological and/or chemical substances; instead, in order to accomplish this, the code must may be transmitted from the device for reading a carrier

medium to the administrative center at which the arrangement associated with the code is-may be determined. While the person may be thus able to determine whether or not a positive reaction of the analyte to some kind of biological and/or chemical substance has occurred, it may not be possible for the person to determine which biological and/or chemical substance is involved. In order to cover the cost of production for of the carrier media, or of the biological and/or chemical substances, the cost of determining a given arrangement associated with a code may, for example, be accounted for in the administrative center.

Preferably, hHowever, the evaluation of the code and determination of the associated arrangement within the administrative center are may be performed at no cost; then As such, a fee is may be charged only in the event if an analyte has reacted positively to the biological and/or chemical substances. This approach provides a health service that which may be implemented in a cost-effective and time-saving manner for the individual but which is also acceptable to the medical insurance companies and the overall healthcare system. The cost-effective availability of the carrier media enables an individual, for example, to test his/her blood or urine on a regular basis for reactions to certain biological and/or chemical substances, whereby a fee is may be incurred only in the event if a reaction has occurred; that is, in the event if the specific person is ill or has a certain condition in some way. The relevant fee or partial fee may, for example, be passed on by the administrative center to the medical insurance companies.

The administrative center <u>preferably may</u> transmits instructions to the reading device as to how the optical detectors are to be set for the specific defined regions. This <u>better measure</u> ensures an <u>optimal</u> a high-quality read-out of the carrier medium.

The method for reading a carrier medium may comprise additional steps. For example, Iin a step e, the reactions of the defined regions are preferably may be detected with the optical detectors

adjusted as best as possible to their optimal setting.

In <u>a step</u> f, the detected signals are advantageously may be transmitted to the administrative center.

In <u>a</u> step g, the arrangement of the biological and/or chemical substances of the carrier medium, and/or the evaluation of the detected signals, are—may be transmitted from the administrative center to the device for reading.

In the an-alternative reading method, the reactions of the defined regions may are first be detected by the optical detectors of the reading device after step b, and then the detected signals are may also be transmitted to the administrative center in step c. The steps related to transmitting the instructions to the reading device mayare thus be eliminated, although here the first reading of the carrier medium may not be as a result, not performed with the optical detectors adjusted as best as possible to their optimal setting.

In <u>the</u> step e, the arrangement of the biological and/or chemical substances of the carrier medium and/or the evaluation of the detected signals <u>are preferably may be</u> transmitted from the administrative center to the reading device.

In an advantageous modification of the method according to the invention, rIn the alternative, requests are may be sent by the administrative center to set certain defined regions in accordance with the detected signals in order to increase the accuracy of measurement and reduce the probability of error.

Preferably, aA request is <u>may be</u> sent by the administrative center, in response to certain detected signals, to read another carrier medium having additional biological and/or chemical substances different from the biological and/or chemical substances on the first carrier medium after application of the analyte. In this way, additional tests may be performed in the case of a reaction to a

given biological and/or chemical substance possibly indicating the presence of a certain disease.

The detected signals and the code for the transmission from the reading device to the administrative center are preferably may be encrypted with a public key. This measure offers additional security for the data transfer while also providing to the administrative center a means for decrypting the data.

The transmission of the detected signal and code to the administrative center are preferably may be error-protection-coded. This measure provides a higher level of security for the data transfer.

These and other objects, features and advantages of the present invention will become more apparent in light of the following detailed description of preferred embodiments thereof, as illustrated in the accompanying drawings.

The following discussion explains the invention in more detailed based on the figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. igure 1 shows illustrates a first embodiment of a carrier medium;

FIG. igure 2 shows illustrates a second embodiment of a carrier medium;

FIGS igure 3aA and 3B shows illustrate a third embodiment of a carrier medium; and

Figure 3b shows a carrier medium corresponding to the carrier medium of Figure 3a;

FIG. igure 4 is a perspective view of a device for reading athe carrier medium of FIGS. 1-3A,3B.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG.igure 1, there illustrated is shows an embodiment of a carrier medium 10 according to the invention. Carrier medium 10 is essentially composed of, e.g., a rectangular film

strip on which defined regions 11 are aligned on an essentially square grid 15. The Ccarrier medium 10 may be approximately the size of a check card or credit card. A code 12 may be located on one narrow end of the carrier medium 10, the code being in the exemplary form of a numerical code. The Ccode 12 here may be located at any desired site on the carrier medium 10. A barcode or alphanumeric code may also be used in place of the numerical code 10.

-Biological and/or chemical substances are may be applied within the defined regions 11 of carrier medium 10, whereby each of the individual defined regions 11 may contains a different biological and/or chemical substance. Preferably, sSeveral hundred defined regions 11 are may be located on the carrier medium 10 such that the naked eye may not be able to detect the defined regions 11. The naked eye is-thus may not be able unable-to recognize which biological and/or chemical substance has been applied to which defined region 11. The Ccode 12 may provides the information as to which substance is located in which region 11. This information may not, however, be directly accessible to the user of the carrier medium 10.

The Carrier medium 10 may has have a temperature sensor 17 to. This sensor records the ambient temperature of the carrier medium 10. Certain biological and/or chemical substances must may only be stored at certain temperatures. In the event a maximum temperature or minimum temperature has been exceeded, the biological and/or chemical substances react to form different substances, and are thus may no longer be usable for the desired test. The information as to whether or not the specified temperature range has been maintained may be is-accessible from the temperature sensor 17 and may be retrieved by the device for reading the carrier medium 510.

Referring to FIG.igure 2, there illustrated is a second shows another embodiment of a carrier medium 20-according to the invention. The Garrier medium 20 may is also be composed of an essentially rectangular film strip on which biological and/or chemical substances have been applied

within the defined regions 21 of the film strip. Unlike the embodiment of FIG. igure 1, the defined regions 21 in FIG. 2 here are may not all be precisely aligned in an essentially square grid 25. Some of the defined regions 21 are may be located precisely at the intersection points of the grid 25, whereas other defined regions 21 may deviate, either horizontally or vertically, from the intersection positions provided by points of the grid 25. The Bbiological and/or chemical substances may be are arranged within the defined regions 21; hHowever, due to the use of large number of several hundred of the defined regions 21, the regions 21 are of correspondingly small size so that the naked eye may be is unable to detect which biological and/or chemical substance is located in which of the defined regions 21. The pattern created by the deviations of defined regions 21 from the intersection points of grid 25 may represent a code indicating which biological and/or chemical substance is located in which of the defined regions 21.

In a method according to the invention for producing the carrier media, not all of the carrier media may be are of identical form. For example, FIGS igures 3aA and 3bB illustrate show two different carrier media 30 and 30', respectively, that may be made from the same production process. In the method-according to the invention, a set of identical carrier media may be is first produced with a first arrangement of biological and/or chemical substances in defined regions 31, as illustrated in FIG. 3A. The Ddefined regions 31 may be are arranged in an essentially rectangular grid. The biological and/or chemical substances are designated in FIGS. 3A and 3B by capital letters A through I. A different biological and/or chemical substance is thus may be located in each of defined regions 31 in FIG. 3A. The cCarrier mediuma 31 are may also be equipped with a temperature sensor 37.

For <u>simplicity</u>the sake of illustrative <u>simplification</u>, the carrier medium 30 of FIG. 3A is illustrated with has only nine defined regions 31. However, the carrier medium 30 according to the invention may havehas, for example, 500 defined regions 31 which are arranged in a grid defined by

a 25 x 20 matrix.

In theis first exemplary set of carrier media, theis arrangement of the biological and/or chemical substances may be is identical. However, all of the carrier media 30 in the first set of carrier media are distinguished by a code 32 which is imprinted on one of the narrower ends of carrier medium 30. For example, if code 32 is a seven-digit number, a maximum of one ten million carrier media 30 could be produced with the first arrangement of biological and/or chemical substances such that each carrier medium 30 has a different code. In the present example, the first set of carrier media 30 may is designed to comprise 10,000 media which are may be numbered by numerical codes 1 through 10,000. Information may be stored in the administrative center indicating that carrier media 30 with codes 1 through 10,000 have the first arrangement of biological and/or chemical substances.

In a second exemplary set of carrier media 30' illustrated in FIG. 3B, the arrangement of biological and/or chemical substances has been modified. The biological and/or chemical substance A, which in the first set of carrier media 30 in FIG. 3A in defined region 31 is located at the top left, is now located within defined region 31' in FIG. 3B at the center of the top line. The position of each the subsequent biological and/or chemical substances B-I may has also bebeen modified. This exemplary arrangement of biological and/or chemical substances within the defined regions 31' of FIG. 3B may be is identical for all of the carrier media 30' of the second set of carrier media. The Ccarrier media 30' of the second set of carrier media are similarly distinguished by a code 32' which may be is imprinted on one of the narrower ends of carrier medium 30'. The Here codes 32' are may be used for the second set of carrier media 30', and may be which codes are different from the codes 32' used with of the first set of carrier media 30'. For example, the second set of carrier media 30' may also have 10,000 media which are numbered with codes 10,001 through 20,000.

Each carrier medium thus receives a different code, although multiple carrier media may have

an identical arrangement of biological and/or chemical substances within the defined regions. Each carrier medium produced is therefore different in that each medium has its own unique code. The number of possible different carrier media may be determined by the number of biological and/or chemical substances on the carrier medium and by the maximum number of different codes. If a carrier medium has 500 different biological and/or chemical substances, the result is 500! different arrangements for the biological and/or chemical substances, whereby in the case of a seven-digit numerical code one-ten million different codes may be provided for each arrangement.

In order tTo ensure that, after the production of, for example, 200 sets of carrier media with the same arrangement, only carrier media having different arrangements of biological and/or chemical substances are may be contained in one pack, 100 sets for example may be are randomly selected from the 200 sets, and from these 100 sets one carrier medium each may be selected, after which the carrier media thus selected may be are packed in one pack. The selection of the sets and carrier media may be is implemented using a random number generator.

Use of the carrier media according to the invention consists in comprises applying an analyte, for example the blood or urine of a patient, to the surface of the carrier medium. Biological and/or chemical substances which may be used include DNA, RNA, proteins, and antibodies. If the analyte contains the corresponding "counterpart" to the biological and/or chemical substance, a reaction takes place which is generally manifested as a change in color of the corresponding defined region. The color changes may, for example, lie in the visible region of the spectrum, or they may also lie within the infrared or ultraviolet regions. Given that there are several hundred defined regions on one carrier medium the size of an ATM-credit card, it is may not be possible for the naked eye to detect the reactions of the analyte with the biological and/or chemical substances; Thus, referring to FIG. 4, and the carrier medium 30 may be is therefore placed, after application of the analyte, into a device

50 for reading the carrier medium. To this end, The device 50 may have has-a drive system, analogous to a disk drive, in which carrier medium 30 is moved into the read position relative to the device 50 (see Figure 4). Once the carrier medium 30 is in the read position, optical detectors, for example semiconductor chips, are located above the individual defined regions 31, which detectors detect the color changes of defined regions 31. However, the device 50 may is-not be capable of assigning the detected signals to the biological and/or chemical substances A through I applied to defined regions 31 of the carrier medium 30 of FIG. 3A. For this purpose, a means may must be attached to device 50 which reads code 32 of carrier medium 30 and transmits it to the administrative center.

In a first method, the detected signals for defined regions 31 are transmitted along with the code 32. The assignment of relating the code 32 to the arrangement of biological and/or chemical substances A through I within the defined regions 31 of the different carrier media 30, 30' may be is stored in the administrative center. Thus, It is thus the administrative center may that determines for which biological and/or chemical substances A through I a reaction has taken place with the analyte. The administrative center may then sends the result back to the device 50 and, depending on the situation, may indicates whether additional carrier media, such as those with different biological and/or chemical substances, are to be analyzed. For example, if on the initially analyzed carrier medium a positive reaction has been found for a certain biological and/or chemical substance, it may be appropriate to analyze the analyte for additional biological and/or chemical substances which were not present on the first carrier medium. In addition, the administrative center may be is able to instruct the device 50 reading a carrier medium as to how the optical detectors should be optimally set-located in regard to the given arrangement of biological and/or chemical substances A through I.

If necessary, testing ean-may be repeated on the carrier medium 30 using the optimized-located

optical detectors.

In a second method, the device 50 may first reads the code 32 of the carrier medium 30 and then may sends the code this to the administrative center. The administrative center may determines the associated arrangement of biological and/or chemical substances A through I from the code 32 and may then instructs the device 50 as to how the optical detectors for this carrier medium 30 should be located optimally set. The Device 50 may then performs the read procedure and detects the color signals emitted by defined regions 31. These may be are subsequently sent to the administrative center which may determines whether, and if so which, of biological and/or chemical substances A through I have reacted with the analyte.

On the carrier medium 30, information is may be provided within the code 32 about the expiration date of the carrier medium 30, which information is, for example, present as a supplementary six-digit code number attached to the seven-digit code number 32 containing the information about the arrangement of biological and/or chemical substances A through I within defined regions 31. The Ddevice 50 may reads this code and issues a warning if the expiration date has already been passed.

In addition, the device 50 may reads the information from temperature sensor 37 and may issues a possible warning in the event if the specified maximum or minimum temperature has been exceeded at any time while the carrier medium 30 was being stored.

Transmission of the data from the device 50 to the administrative center may proceeds after the data has been encrypted using a public key. This key may be is-provided by the administrative center, and thus only the administrative center may be is-able to decrypt the data. In addition, transmission of the data may be is-error-protection-coded so that any transmission errors may be immediately discovered and eliminated.

In order tTo finance the production of the carrier media and, specifically, the biological and/or chemical substances, while at the same time providing the most inexpensive possible medical screening test for any person, provision may is-made whereby the evaluation of the codes and determination of the associated arrangement of the carrier media may be is-performed at no charge within the administrative center, and a fee may be is-charged only in the event if one of the biological and/or chemical substances has reacted with the analyte.

Although the present invention has been shown and described with respect to several preferred embodiments thereof, various changes, omissions and additions to the form and detail thereof, may be made therein, without departing from the spirit and scope of the invention.

What is claimed is: